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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
.10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159

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Squire, Sanders & Dempsey, L.L.P.
Suite 300
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San Francisco, CA 94111

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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06/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,139	Applicant(s) DESNOYER ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/29/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/22/2007 has been entered. The amendments to the claims filed 03/22/2007 have been entered.

Claim Objections

Claims 6-7,17-18,28-29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiply dependent claim. See MPEP § 608.01(n). To expedite the examining process the examiner treated claim 6 as though it depended only upon claim 5, claim 17 as though it depended only upon claim 16 and 28 as though it depended upon claim 27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti (WO 03/022323 A1, cited by applicants in IDS filed 11/06/2006) and in view of Roby et al. (WO 98/32398 A1, cited by applicant in IDS filed 11/06/2006).

Pacetti discloses a coating for reducing the rate release of drugs from stents in which the stent includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the stent. See abstract. The polymers include polyurethanes with a polydimethylsiloxane soft segments, poly(vinylidene fluoride-co-methacrylic acid), styrene-ethylene-styrene block copolymer, polytetrafluoroethylene ect. See [0020]-[0021] and claims 11,16-17. The therapeutic agents included anti proliferative-substances, antibiotics, paclitaxel ect. See [0028].

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Regarding the limitation that the implantable device is applied to a solution of PEA and a low surface energy, surface blooming polymer, Pacetti discloses that the composition can be applied by any conventional method including spraying the composition on the device or by immersing the device in the composition. See [0023]. Regarding claims 45-52 Pacetti discloses several methods of using the coated stents including treatment of obstructions caused by tumors and for treating occluded regions of blood vessels caused by abnormal or inappropriate migration and proliferation of smooth muscle tissue cells, thrombosis and restenosis. See [0032].

Pacetti does not disclose the use of PEA in combination with the crystalline polymers (same as low surface energy polymer or low surface energy, surface blooming polymer), to produce a coating containing a therapeutic for a stent.

Roby discloses the preparation of polyesteramides and surgical devices fabricated from them. See abstract and pag 1 lin 1-21. Roby is used mostly for the disclosure within that polyesteramides can be used as a coating for surgical devices and the polyesteramide surgical devices could also incorporate therapeutic agents such as antimicrobial agents. See pag 6 lin 3-pag 8 lin 18. The polyesteramide compositions could also be blended with other absorbable or non-absorbable compositions. Roby disclosed that the advantages or significance of PEA for use in medical devices was the susceptibility of their ester linkages to hydrolyze, conferring upon PEA the ability to be absorbed or resorbed by the body and the amide linkages confer upon them desirable mechanical properties. Regarding claims 53-58 it is obvious that since both the coatings described in Pacetti and Roby are used for medical devices for use in the body the

coating would be biologically benign and since the combination of the coatings described in the references above are the same as applicants claimed invention it is also obvious that the coatings would have the same properties, including biological properties. Regarding applicants newly amended claims which enter the proviso that both the low surface energy, surface blooming polymer or polymer additive comprises a PEA miscible block or a PEA miscible backbone, since by combination the two references disclose the same type of polymers and the same type of polymer additives the claim limitation is obviously met because the same compounds will have the same miscibility properties. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Pacetti disclosed the use of both the same low surface energy polymers and low surface energy, surface blooming polymers for a stent coating containing a therapeutic as applicants claims while Roby disclosed that coatings for surgical devices containing PEA and therapeutics was already well known in the art at the time of the invention. The motivation to combine the above documents would be to produce and

use a coated stent in which the coating comprised a therapeutic, PEA and a highly crystalline hydrophobic polymer (same as applicants low surface energy polymer). The advantage of such a coating would be that the combination would provide a biologically absorbable coating with desirable mechanical properties from the PEA polymer disclosed in Roby and a controlled release of the therapeutic from the crystalline polymers disclosed in Pacetti. One of ordinary skill in the art would have a reasonable expectation of success in combining the PEA polymers of Roby with the polymers of Pacetti because both polymers are disclosed as useful in the same field of endeavor being polymers useful as coatings for a stent. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 03/22/2007 have been fully considered but they are not persuasive.

Applicants asserts that neither Pacetti or Roby disclose a low surface energy surface blooming polymer or polymer additive that includes a miscible PEA block or backbone.

The relevance of this assertion is unclear. Since by combination the two references disclose the same type of polymers and the same type of polymer additives the claim limitation is obviously met because the same compounds will have the same miscibility properties. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or

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obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER